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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,326	02/24/2004	Fredric J. Cohen	X-11057C	9685

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ELI LILLY & COMPANY
PATENT DIVISION
P.O. BOX 6288
INDIANAPOLIS, IN 46206-6288

EXAMINER	
ANDERSON, JAMES D	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
01/10/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary	Application No.	Applicant(s)	
	10/785,326	COHEN ET AL.	
	Examiner	Art Unit	
	JAMES D. ANDERSON	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19 and 145-156* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19 and 145-156* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/8/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

Applicants' response, filed 11/8/2010, is acknowledged and entered. No claim amendments were submitted. Claims 19 and 145-156 are pending and under examination.

Response to Arguments

Applicants' arguments, filed 11/8/2010, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants traverse the Obviousness-Type Double Patenting rejections set forth in the prior Office Action and reiterated below, asserting that the patients treated by the practice of the presently claimed methods would not inherently result by the practice of the patients treated by the claimed methods of the '740, '232, '168, and '847 patents. Applicants further argue that U.S. Patents 6,103,740 and 6,008,232 have expired due to nonpayment of the maintenance fees.

With regard to the expired '740 and '232 patents, Applicants' arguments are persuasive. The ODP rejections over USP Nos. 6,103,740 and 6,008,232 are withdrawn solely in view of the fact that these patents have expired due to nonpayment of maintenance fees.

With regard to the '168 patent, Applicants' arguments are not persuasive. Applicants argue that the '168 patent is directed to a method of lowering serum cholesterol levels in a post-menopausal female comprising administration of 60 mg/day to a post-menopausal female in need thereof an effective amount of raloxifene HCl. Applicants argue that there is no teaching and no expectation in the '169 patent that women, who are diagnosed as being in need of reduction of the likelihood of incurring or developing estrogen-dependent breast cancer, represent all post-menopausal women. Applicants further argue that there is no teaching and no expectation in '168 that women, who are diagnosed as being in need of such lowering of serum cholesterol, represent all postmenopausal women. In response, the Examiner respectfully submits that because both the '168 patent and the instant claims encompass administration of 60 mg/day

raloxifene to post-menopausal women, there is an overlapping patient population. Applicants have presented no factual evidence that post-menopausal women in need of lowering of serum cholesterol are also not in need of reduction of the likelihood of incurring or developing estrogen-dependent breast cancer. It is the Examiner's position that ALL post-menopausal women are in need of reduction of the likelihood of incurring or developing estrogen-dependent breast cancer.

With regard to the '847 patent, Applicants' arguments are not persuasive. Applicants argue that the '847 patent is directed to a method of inhibiting bone loss or bone resorption comprising administration of 60 mg/day to a post-menopausal female in need thereof raloxifene HCl. Applicants argue that there is no teaching to diagnose or screen patients for reducing the likelihood of incurring or developing estrogen-dependent breast cancer. Applicants argue that there is no teaching and no expectation in the '847 patent that women, who are diagnosed as being in need of reduction of the likelihood of incurring or developing estrogen-dependent breast cancer, represent all post-menopausal women. Applicants further argue that there is no teaching and no expectation in '847 that women, who are diagnosed as being in need of such inhibiting bone loss or bone resorption, represent all postmenopausal women. In response, the Examiner respectfully submits that because both the '847 patent and the instant claims encompass administration of 60 mg/day raloxifene to post-menopausal women, there is an overlapping patient population. Applicants have presented no factual evidence that post-menopausal women in need of inhibiting bone loss or bone resorption are also not in need of reduction of the likelihood of incurring or developing estrogen-dependent breast cancer. It is the Examiner's position that ALL post-menopausal women are in need of reduction of the likelihood of incurring or developing estrogen-dependent breast cancer. In fact, claims 153-156 of the instant claims clearly and unequivocally encompass treatment of post-menopausal women with osteoporosis.

Further, Applicants clearly and unequivocally contemplate that the methods of their invention are intended to be administered to the entire population. In this regard, Applicants disclose that the current invention provides methods for the prevention of breast cancer, including de novo breast cancer (page 9, lines 9-11; claims 147 and 148).

With regard to the claimed "diagnosed as being in need of such therapy", all post-menopausal women, including those diagnosed in the '168 and '847 patents, are clearly in need of reducing the likelihood of incurring or developing estrogen-dependent breast cancer.

Information Disclosure Statement

Receipt is acknowledged of the Information Disclosure Statement filed 11/8/2010. The Examiner has considered the references cited therein to the extent that each is a proper citation. Please see the attached USPTO Form 1449.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 19 and 145-152 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,103,740 is **withdrawn** in light of the fact that the '740 patent expired due to nonpayment of maintenance fees. See Applicants' Remarks filed 11/8/2010 at page 7.

The rejection of claims 19 and 145-152 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,008,232 is **withdrawn** in light of the fact that the '232 patent expired due to nonpayment of maintenance fees. See Applicants' Remarks filed 11/8/2010 at page 7.

Claims 19 and 145-152 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 11 of U.S. Patent No. 5,610,168. Although the conflicting claims are not identical, they are not patentably distinct from each other because the active method step of the '168 patent claims comprises administration of raloxifene hydrochloride (claim 11) to a post-menopausal woman (claim 4) via administration of 60 mg/day (claim 6). Accordingly, the instantly claimed effects of such administration (i.e., reducing the likelihood of incurring or developing estrogen-dependent breast cancer) would inherently result from the practice of the '168 patent method claims.

Regarding "administration" as recited in the '168 patent claims, the specification of the '168 is used as a dictionary to define such administration. In this regard, the inventors teach that the term of period of time of administration to a human will be at least 6 months, normally at least one year, and preferably on a continual basis (col. 8, lines 24-30). The inventors further teach oral administration as recited in the instant claims (col. 7, lines 61-64).

Claims 19 and 145-156 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-7, and 12 of U.S. Patent No. 5,478,847. Although the conflicting claims are not identical, they are not patentably distinct from each other because the active method step of the '847 patent claims comprises administration of raloxifene hydrochloride (claim 12) to a human diagnosed with osteoporosis (claim 2), to a post-menopausal woman (claim 3), via administration of 60 mg/day (claim 7), and wherein the raloxifene is administered prophylactically (claim 5). Accordingly, the instantly claimed effects of such administration (i.e., reducing the likelihood of incurring or developing estrogen-dependent breast cancer) would inherently result from administration of 60 mg/day of raloxifene hydrochloride to a post-menopausal woman having osteoporosis as claimed in the '847 patent.

Regarding "administration" as recited in the '847 patent claims, the specification of the '847 is used as a dictionary to define such administration. In this regard, the inventors teach that the term of period of time of administration to a human will be at least 6 months, normally at least one year, and preferably on a continual basis (col. 8, lines 24-30). The inventors further teach oral administration as recited in the instant claims (col. 7, lines 61-64).

Regarding the Obviousness-Type Double Patenting rejections set forth supra, Applicants' recitation of different biological effect of administration of 60 mg/day raloxifene hydrochloride to a post-menopausal woman as claimed in the cited patents does not distinguish the claimed method from the methods recited in the patent claims.

Practice of the methods recited in the cited patent claims will inherently result in reducing the likelihood of incurring or developing estrogen-dependent breast cancer in the treated patients because the same compound is being administered in the same amount to the same patients. In other words, Applicants recognition that administration of 60 mg/day of raloxifene hydrochloride to post-menopausal women as recited in the claims of the above cited patents reduces the incidence of estrogen-dependent breast cancer in those patients, in addition to lowering serum cholesterol ('168 patent) and/or inhibiting bone loss or bone resorption ('847 patent), does not distinguish the claimed methods from those recited in the above patent claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES D. ANDERSON whose telephone number is (571)272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James D. Anderson/
James D. Anderson, Ph.D.
Primary Patent Examiner, Art Unit 1614
UNITED STATES PATENT AND TRADEMARK OFFICE
400 Dulany Street
Alexandria, VA 22314-5774
Tel. No.: (571) 272-9038